Economists have devoted relatively little attention to analyzing how government officials actually enforce regulation. This is a significant omission, since the efficacy of regulatory enforcement and the effects of regulation on economic outcomes may depend on how regulators regulate. This article sheds light on these issues by examining how the fledgling Food and Drug Administration (FDA) enforced the Pure Food and Drugs Act from 1907 to 1938. I argue that because the FDA’s ability to enforce this law through deterrence was limited, effective enforcement could be obtained only in those instances where the agency had the capacity to offer benefits to compliant firms in the way of quality certification or direct assistance in improving product quality. The available evidence on the FDA’s enforcement activities is consistent with this prediction. The analysis presented may help to explain why contemporary regulatory agencies spend considerable resources on advisory enforcement activities.

1. Introduction

At present, the economics literature contains relatively few empirical studies of how government officials enforce regulation. While much scholarship has analyzed the interest group determinants of regulation, and a large literature has also investigated the effects of regulation on the performance of particular markets, few economists have studied how regulators attempt to obtain compliance with regulatory objectives. The political science literature, in contrast, is not lacking in this regard. Several articles have focused on the political determinants of certain regulatory actions (Weingast and Moran, 1983; Weingast, 1984; Moe, 1985; Magat, Krupnick, and Harrington, 1986; Olson 1995, 1996a, 1996b). Additionally, a new body of work investigates the nature of firm-regulator interactions and regulatory strategy (Carpenter, 2004; Carpenter and Ting, 2005; Gordon and Hafer, 2005). Nevertheless, we still know little in general about how real-world regulators actually behave. This is a significant
omission for two reasons. First, how regulations and laws are enforced is an important economic question that has been the subject of much theoretical work but far less empirical scrutiny. Second, the efficacy of regulatory enforcement and the effect of regulation on economic outcomes may depend partially on how regulators regulate (Scholz and Gray, 1997).

According to the economic approach to law enforcement, economic actors will comply with regulation if and only if the benefits of compliance with regulation exceed the costs. Curiously, the theoretical literature on the economics of law enforcement focuses exclusively on the effect of punishment for non-compliance on the behavior of economic actors (Becker, 1968; Stigler, 1970; Polinsky and Shavell, 2000). The focus of this scholarship is on the design of optimal deterrence strategies. Enforcement, according to this perspective, entails setting the appropriate fine and conducting the optimal amount of monitoring. Does the use of legal penalties to alter behavior in this fashion really characterize the enforcement of most laws and regulations? Given that enforcement of regulation through deterrence often requires the threat that violators will be taken to court, and given that it is generally costly to use the courts to enforce laws and regulations ex post (i.e., after the offense has been committed), how effective or widespread is this kind of enforcement strategy? If regulators can offer benefits to economic actors, perhaps by playing a coordinating role in helping firms or individuals solve market failures or overcome collective action problems, then compliance with the objectives of regulation can be obtained ex ante, and the courts can be avoided (Scholz, 1984; Scholz and Gray, 1997). Does this alternative “advisory” approach to regulatory enforcement furnish a more accurate portrait of how compliance with regulation is achieved in practice?

This article deals with these issues through a careful analysis of the enforcement of the Pure Food and Drugs Act of 1906. Under this law, officials from the fledgling Food and Drug Administration (FDA) were given the authority to regulate the food and drug industry with the goal of stemming interstate trade in adulterated and misbranded products. An analysis of how officials from the FDA attempted to enforce this law is of interest. First, scholars disagree about whether the FDA was actually capable of enforcing the provisions of this law.

1. See Polinsky and Shavell (2000) for an overview of the theoretical literature on enforcement.
2. Indeed, in the literature, the word “enforcement” nearly always connotes deterrence. Throughout this article, I use the term “enforcement” to refer more broadly to all activities that the regulatory agency engages in to facilitate compliance with regulatory objectives.
3. Until the late 1920s, the organization that we know today as the FDA was the Bureau of Chemistry, an agency within the US Department of Agriculture. In 1927, the regulatory portion of this agency was renamed the Food, Drug and Insecticide Administration. In 1930 the name was shortened to the Food and Drug Administration. Henceforth, I will refer to the Bureau of Chemistry and its successor organizations as the FDA.
Hutt and Hutt (1984) believe that because the FDA lacked authority to set legally binding food and drug standards, and because the penalties for violating the law were small, effective enforcement was not possible until 1938, when Congress enacted the (much stricter) Food, Drug, and Cosmetics Act. Coppin and High (1999) argue that early efforts to enforce this law were hampered by the bureaucratic ambitions of Harvey Wiley, the first chief of the FDA. On the other hand, Young (1992) credits the agency’s enforcement efforts for having brought about gradual improvements in the quality of foods available in the marketplace. Hence, an investigation of how the FDA attempted to enforce the law may also inform the debate about the early FDA’s effectiveness.5

Second, an analysis of how the Pure Food and Drugs Act was enforced may shed light on the administration of current regulations. Agencies like the EPA, FCC, OSHA, and the contemporary FDA spend considerable resources consulting with firms, developing “Good Manufacturing Practices” guidelines, and engaging in other forms of ex ante advisory enforcement. Why does advisory activity play an important role in the enforcement of so many regulations? Apart from Scholz and Gray (1997), little attention has been paid to the role that these alternative enforcement strategies can play in achieving regulatory compliance. The lessons drawn from this analysis may therefore help form the basis of a more realistic understanding of regulatory enforcement.

The hypothesis I advance is as follows. Due to the small size of the FDA and weaknesses in the enforcement provisions of the Pure Food and Drugs Act, an enforcement strategy of deterrence through the threat of ex post punishment of firms that violated the law was unlikely to be effective. Hence, the way the FDA induced compliance with the law was to offer benefits to firms who complied ex ante.6 To flesh out the logic of this hypothesis, I develop a very simple

5. Glaeser and Schleifer (2003) develop a model of law enforcement that considers the trade-offs among private litigation, government regulation, a combination of the two, and doing nothing in an environment where economic actors have incentives to subvert the justice system for their private benefit. They argue that in the setting that prevailed in the United States during the Progressive Era, regulation or a combination of regulation and private litigation is optimal. Because regulation lowers the fines needed to induce compliance, regulation reduces firms’ incentive to subvert the judicial system. Hence, these authors argue that regulations like the Pure Food and Drugs Act were adopted in response to corruption of the justice system by large corporations. Although Glaeser and Schleifer offer many interesting insights about the rise of the regulatory state, the lessons from their article are not directly applicable here. First, an examination of the legislative history of the Pure Food and Drugs Act indicates that concerns about the subversion of the justice system by large corporations played a minor role in the enactment of this law (Law and Libecap, 2005). Second, the way these authors characterize regulatory enforcement in their model is too limited. They model regulatory enforcement as a situation where a high level of precaution is required ex ante and a fine is levied on firms that are caught by the regulatory agency ex post. In contrast, I also consider the possibility that regulators may offer benefits to firms that are known to comply ex ante. When regulators have this capacity, Glaeser and Schleifer’s characterization of regulatory enforcement is too narrow.

6. Greater compliance could also be achieved if the FDA’s ability to deter violations (for instance by increasing the number of inspectors, or by strengthening the deterrence provisions of the law) were enhanced, but it seems reasonable to assume that the agency was probably unable to influence these factors significantly.
model of firm compliance behavior in which there is asymmetric information about product quality and the regulator can engage in both traditional ex post enforcement (deterrence) and advisory ex ante enforcement (quality certification or direct assistance in improving product quality). The main prediction of this model is that, for a given expected penalty from ex post enforcement, compliance with regulation is more easily obtained when the regulator can also engage in an advisory enforcement policy. In other words, compliance is facilitated by the regulator’s ability to offer benefits to firms through advisory enforcement activities. I then test this hypothesis through a close examination of qualitative and quantitative information on the FDA’s enforcement work from 1907 to 1938. Consistent with the model, the evidence suggests that when the FDA could play an advisory role of certifying product quality or helping firms improve the quality of their products ex ante, the FDA was able to induce significant compliance with the Pure Food and Drugs Act, while in those instances where the FDA could not offer such services, compliance was generally not obtained. Hence, the evidence presented in this case study suggests that, at least in some instances, an advisory approach to regulatory enforcement may be a necessary component of an effective enforcement strategy.

The remainder of this article is structured as follows. Section 2 discusses the origins of the federal Pure Food and Drugs Act and the nature of the market failure that generated a demand for regulation of the food and drug trade. Section 3 presents a simple model of firm compliance behavior in a setting in which there is asymmetric information about product quality and in which the regulator can engage in deterrence or advisory enforcement to induce firm compliance. Section 4 presents quantitative information on the FDA’s efforts to enforce the law through deterrence. Section 5 discusses why an enforcement strategy of pure deterrence was not effective, using the agency’s efforts to regulate the patent medicine industry as a case study. Section 6 details the alternative advisory approach that the FDA took to enforcing the law in other segments of the industry and shows that when an advisory option was available, compliance was often achieved. Finally, Section 7 concludes the article.

2. The Origins of Federal Food and Drug Regulation

During the thirty years before the passage of the Pure Food and Drugs Act, state governments began to regulate aspects of the food and dairy trade. Although the specifics of these laws varied considerably across states, their general purpose was to require manufacturers and distributors to accurately label their products. Producers and distributors who failed to indicate the presence of “impurities” in their wares could be fined and even imprisoned under charges of adulteration (i.e., cheapening of food or drugs through the addition of impurities). While the enforcement of some of these laws undoubtedly enabled some elements of the food and dairy trade to gain a competitive advantage over their rivals (Libecap, 1992; Dupré, 1999), the political pressure for “pure food” regulation also arose because of growing uncertainty about food quality. Technological advances in food processing and manufacturing, combined with
urbanization that made households more dependent on the market for their food, raised information costs to consumers about the quality of food products. High information costs allowed manufacturers and distributors to adulterate and misbrand their wares in an effort to obtain dear prices for cheap items. Consistent with Akerlof (1970), asymmetric information about product quality gave rise to a lemons problem in which low-quality products drove out higher quality products. Because technological advances made it possible for food manufacturers to adulterate their products in ways that consumers could not easily detect even after consumption, reputation mechanisms, which rely on ex post verifiability of product quality, may not have been sufficient to ensure the delivery of quality food items (Darby and Karni, 1973; McCluskey, 2000). State government regulation was a viable solution to this asymmetric information problem because state governments employed chemists and other scientific experts who had a comparative advantage over consumers in detecting food adulteration. Regulation provided consumers with an assurance of purity, since many forms of food adulteration could be detected only in a laboratory. Thus, an important motivation for state pure food regulation was its potential to reduce information costs in the market for food products (Law, 2003).

Interest in federal regulation of the food industry emerged almost contemporaneously with an interest in state regulation, but an effective political constituency in favor of a federal law took much longer to build. Several factors contributed to the rise of state as opposed to federal pure food regulation during the late 1800s. First, since many products were produced and sold in the same state, the state was sometimes the most efficient regulatory unit. This was especially true for dairy items, which could not be transported easily for long distances. Second, although manufacturers from geographically disparate regions may have benefited from uniform federal regulation, high collective action costs prevented producers in different regions from coming together and lobbying for a uniform federal law. Hence, many industry groups looked first to state governments to regulate their products. Third, until the early twentieth century, consumer interest in pure food issues was more powerful at the state

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7. Ménard (1996) argues that quality certification clubs can also play a role in policing product quality and reducing informational asymmetries. These kinds of organizations did not emerge in the food industry in early-twentieth-century America. Since most food manufacturers were small and geographically dispersed, high collective action costs generally precluded the formation of such clubs. Additionally, effective enforcement of quality standards within a club requires that its members agree on very explicit guidelines regarding production conditions and production processes. Because the science of food manufacturing and processing was still in its infancy, such guidelines did not yet exist for much of the food trade. Indeed, as discussed in this article, the FDA, through its enforcement work, played a key role in developing these standards. While trade associations did exist at this time, their efforts appear to have been focused primarily on obtaining legislation that disadvantaged competing products, which contributed to political stalemate over federal regulation (Wood, 1986).

8. As Young (1989) notes, federal “pure food” bills were introduced in Congress throughout the 1880s and 1890s, but it was not until the early 1900s that the enactment of a federal pure food law became a real possibility.
and local level than at the federal level. It was natural for these groups to ask their state legislatures for regulation before going to Congress with their demands (Goodwin, 1999). Thus, an effective political constituency in favor of regulation found its first expression at the state rather than the federal level.

By the early 1900s, however, there was mounting political pressure for a federal pure food law. Manufacturers and distributors engaged in interstate trade desired a federal law because compliance with widely varying state laws was costly. State regulators from state food and dairy commissions also desired federal legislation, because the growing importance of interstate trade in food made it costly to enforce pure food regulations at the state level. Organized consumer groups—specifically, the General Federation of Women’s Clubs, the Women’s Christian Temperance Union, and muckraking journalists from newspapers and magazines—also wanted a federal law because of imperfections in state-level enforcement. Additionally, within the federal bureaucracy, officials from the Department of Agriculture—most notably, Dr. Harvey Wiley, Chief of the Bureau of Chemistry—had by the turn of the century secured sufficient “bureaucratic autonomy” to openly champion federal regulation of the food industry (Young, 1989; Carpenter, 2001). Like their counterparts in state agricultural experiment stations and state food and dairy commissions, officials from the Bureau were trained scientists who had the tools to detect food and drug adulteration and felt that their expertise could be useful in protecting consumers from commercial fraud. While there was considerable agreement among these interests about the general desirability of a federal law, initial efforts to secure a law faltered because of infighting among industry groups, state and federal regulators, and politicians regarding the specific provisions that would be included in a federal pure food statute. Muckraking journalism about the quality of patent medicines and meat, as well as considerable bureaucratic entrepreneurship on the part of Wiley, appear to have played important roles in breaking the political stalemate over regulation (Young, 1989, Coppin and High, 1999, Carpenter, 2001, Law and Libecap, 2005).

The 1906 law was reasonably similar to those that were enacted earlier by state governments, except that it was more comprehensive than most state laws, and it applied specifically to food and drug items produced for interstate commerce. Under this law, officials from the FDA were given the authority to inspect food and drug items produced for interstate sale to determine whether these products were adulterated or misbranded. Manufacturers and distributors could be charged for adulteration if their products were found to be unfit for consumption; if any substance had been mixed or packed with it so as to reduce or lower its quality or strength without indication on product labels; if any substances had been substituted wholly or in part for the article without indication on product labels; or if an article was mixed, colored, powdered, coated, or stained in a way that would conceal damage or inferiority without some indication on the product label. Producers were required to disclose the presence of narcotic substances like cocaine or heroin in food and drug products. Certain poisonous ingredients were specifically prohibited from food.
The FDA could charge manufacturers of misbranding if product labels or packages included “any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular.” Under the drug provisions of the law, druggist preparations (i.e., drugs produced for prescription sale) would be deemed adulterated if they differed from the standards of purity set forth in the USP or the NF. Medicine labels were required to indicate the presence of alcohol, narcotics, and other potentially addictive substances. Producers and distributors found guilty of adulterating or misbranding their products could be fined or imprisoned. Officials from the FDA were granted authority to seize adulterated and misbranded products. Hence, at least on paper, the purpose of the federal law, like the state laws that preceded it, was to ensure the accuracy of product labels, to protect the public from foods that were unfit for consumption, and to improve the quality and safety of food and drugs available in the market (Young, 1989:262–72).

3. A Simple Model of Firm Compliance Behavior

As a starting point for an analysis of the enforcement of the 1906 law, I develop a very simple model of firm compliance behavior. As is standard in the literature on regulatory enforcement, I assume that firms comply with the law if the expected benefits of compliance exceed the expected costs of non-compliance and that, by engaging in a policy of deterrence, the regulator influences the costs of non-compliance. However, unlike the standard model, I assume that there is asymmetric information about each firm’s product quality. In the context of the food and drug trade in the early 1900s, the assumption of asymmetric information about quality seems reasonable (Law, 2003; Law and Libecap, 2005). Additionally, in contrast with the standard enforcement framework, I also consider the effect of an ex ante advisory enforcement policy of product quality certification or offering direct assistance to firms in improving product quality on the compliance behavior of firms. This is an important addition to the standard model, which considers only how deterrence affects the firm’s compliance decision.

While I do not directly model the FDA’s objective function, I will assume that the agency’s goal is to improve efficiency in the market for food and drugs by maximizing compliance with the objectives of the law. Maximizing welfare may be in the regulator’s interest because doing so improves bureaucratic reputation (Carpenter, 2001). Regulators may benefit by developing a reputation from their observable success in protecting the public health or in improving the overall quality of food and drugs because doing so increases the resources political officials make available to them, satisfies their sense of “professionalism,” or improves their future career opportunities. Indeed, evidence from the USDA during the Progressive Era as well as, more recently, from FDA drug approval decisions suggests that “reputation-maximization” may be an important motivation for regulatory agencies (Carpenter, 2001, 2002).

The setup of the model is as follows. Each firm in a market consisting of \( n \) identical firms produces one unit of output. This output can either be high
quality (h) or low quality (l). Each firm chooses which level of quality to supply. The costs of producing high- and low-quality output are \(c_h\) and \(c_l\), respectively. Assume that the cost of producing the high-quality output is higher than the cost of producing the low-quality output (\(c_h > c_l\)).

Consumers are willing to pay \(p_h\) for a high-quality output and \(p_l\) for a low-quality output, where \(p_h > p_l\). A firm earns higher profits if it produces a high-quality output and sells it at the high price than if it produces a low-quality output and sells it for the low price (i.e., \(p_h - c_h > p_l - c_l\)). Additionally, let us assume that social welfare is higher when the higher quality output is produced and consumed.

There is asymmetric information about product quality such that consumers cannot distinguish high- from low-quality output ex ante. Consumers have a belief that some fraction \(q\) (where \(0 < q < 1\)) of firms produce the high-quality output, and that the remaining fraction \((1 - q)\) of firms produce the low-quality output. Assuming that consumers are risk neutral, the price they will be willing to pay for any randomly chosen unit of output, given their belief \(q\), is \(p_r = qp_h + (1 - q)p_l\). If consumers believe that all firms are producing the high-quality output \((q = 1)\), they are willing to offer a price of \(p_h\). On the other hand, if consumers believe that all firms are producing at the low-quality level \((q = 0)\), they will offer a price of \(p_l\).

Suppose that firms have no credible mechanism for committing to produce the high-quality output and that there is no regulator. If this is the case, the equilibrium outcome is one in which each firm chooses to produce the low-quality output (l) and consumers are willing to pay only a low price (i.e., \(p_r = p_l\)). As long as each firm perceives that it has a negligible effect on the average level of quality in the market, an outcome where each firm produces at the high-quality level and receives a high price cannot be sustainable. This is because, for any given price, an individual firm can always increase its profits by producing the low-quality output. Because consumers know that each firm faces this incentive to cheat on quality, it is rational for consumers to hold a belief that \(q = 0\) and to offer a price of \(p_l\). When asymmetric information is combined with the lack of a credible commitment mechanism, it gives rise to an outcome where consumers are willing to pay only a low price and the low-quality level is chosen by each firm. This outcome is sub-optimal for producers as well as for society.

Suppose now that a law (the Pure Food and Drugs Act) is enacted that makes it illegal to produce low-quality output; furthermore, a government agency (the FDA) is empowered to maximize compliance with this objective. Assume that the FDA, unlike consumers, can easily verify product quality. The FDA has three regulatory enforcement options at its disposal:

1. Deterrence: The FDA inspects product quality after products reach the market, takes suspected offending firms to court and, if the firms are convicted, the courts impose a fine on them. Since it is costly to inspect quality, there is only some probability \((0 < r < 1)\) that an offending firm is caught. Additionally, since the courts are imperfect, there is only some
probability ($0 < s < 1$) that an offending firm is convicted. The size of the fine the court can impose on convicted firms is $f$. Hence, the expected penalty from being caught, convicted, and fined is $rsf$. Assume that deterrence produces no “false negatives”: high-quality producers do not run the risk of being prosecuted by the FDA and convicted by the court.

2. Technical assistance: The FDA offers firms a lower cost technology for producing high-quality output. Firms who come to the FDA for technical assistance can produce high-quality output at a cost of $c_{FDA}$ where $c_l < c_{FDA} < c_h$. Assume that consumers cannot observe which firms receive technical assistance from the FDA and which firms do not.

3. Certification: The FDA gives firms that produce high-quality output the option of voluntarily submitting their product to the FDA for a “stamp of approval.”9 Because certification is observable by consumers, consumers will be willing to pay the high price ($p_h$) for products that are certified.

Since option (1) involves catching offenders after production has taken place and goods have reached the market, I call the deterrence option ex post enforcement. Since options (2) and (3) involve ensuring compliance before products are marketed, I refer to these strategies as ex ante enforcement. Assume that the law requires that the FDA engage in option (1) but that options (2) and (3) can be pursued at the agency’s discretion.10

If producers are risk neutral, they will comply with the law (i.e., produce high quality) if the expected net benefits of compliance exceed the expected net benefits of non-compliance. I now examine how these different enforcement options affect a firm’s decision as to whether to comply with the law.

3.1 Case 1: Pure Deterrence

Suppose that the FDA follows an enforcement strategy of pure deterrence. An equilibrium outcome in which each firm complies with the law (i.e., produces a high-quality output) and consumers offer the high price will require that

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9. The value of certification will depend on bureaucratic reputation. According to Carpenter (2001), the FDA at this time had already developed a reputation as a scientific agency whose goal was to protect the nation’s health and to improve the quality of food and drugs.

10. As long as deterrence and advisory enforcement are not perfect substitutes, the agency might willingly engage in some of each. In fact, there may be complementarities between deterrence and each of the two ex ante enforcement options. First, by engaging in ex post enforcement, the FDA learns about which aspects of product quality need improving and, indirectly, how to improve quality. Second, ex post enforcement may be needed to make ex ante enforcement effective. The FDA may need to engage in ex post enforcement in order to make sure that those firms who do receive quality certification or technical assistance do in fact produce the high-quality output. Ex post enforcement thus serves as an auditing mechanism. If one were to model this as a repeated game, the threat of ex post enforcement may help support a cooperative equilibrium where firms engage in ex ante compliance.
\[(p_h - c_h) > (p_h - c_l) - rsf\],

which can be expressed as

\[rsf > (c_h - c_l)\].

In other words, if compliance is to occur, the expected penalties for non-compliance must exceed the cost savings from non-compliance. If the expected penalties from non-compliance are smaller than the cost savings from non-compliance, a pure deterrence strategy will not generate an outcome in which all firms produce the high-quality output.

### 3.2 Case 2: Combine Deterrence with an Ex Ante Enforcement Option of Technical Assistance

Suppose that firms can go to the FDA to learn how to produce high-quality output at lower cost, but consumers cannot observe whether a firm has gone to the FDA to learn this cost-saving technology. In this case, an equilibrium outcome in which all firms produce at the high-quality level \(h\) and consumers offer the high price \(p_h\) will require that

\[\left(\frac{p_h}{C255} - c_{FDA}\right) > \left(\frac{p_h}{C255} - c_l\right) / C255 \cdot rsf;\]

which can be expressed as

\[rsf > c_{FDA} - c_l\].

Similar to the previous case, compliance will occur if the expected penalties from non-compliance exceed the cost savings from non-compliance, except that the cost savings from non-compliance are lower than before because of the availability of FDA-supplied technology. For a given expected penalty from deterrence, compliance is therefore more likely than before.\(^{11}\)

### 3.3 Case 3: Combine Deterrence with an Ex Ante Enforcement Option of Certification

Certification gives firms that produce high quality the opportunity to have a “stamp of approval” placed on their output. In other words, certification serves as a credible signal of quality for consumers. Firms that submit their products for certification can thus obtain the high price for their output because certification solves the asymmetric information problem about product quality. Consumers know that any product that is certified is of high quality and that any product that is not certified is of low quality. Hence, there will be an equilibrium outcome in which all firms produce the high-quality output and consumers offer the high price if

\(^{11}\) Case 2 assumes that consumers cannot observe which firms receive FDA assistance. If this is observable to consumers, then this case becomes similar to the third case: receiving technical assistance becomes analytically equivalent to receiving quality certification by the FDA.
\[(p_h - c_h) > (p_I - c_I) - rsf,\]  

which implies that 

\[rsf > (c_h - c_I) - (p_h - p_I).\]  

In other words, compliance occurs if the expected penalties from non-compliance exceed the cost savings from non-compliance less the price premium from compliance. Relative to the pure deterrence case, the expected penalty does not have to be as large to induce compliance because non-compliant firms lose out on the opportunity to earn a price premium for their output.  

4. Evidence of FDA Objectives: Seizures and Prosecutions

In its Annual Report from 1919 to 1938, the FDA published information on the number of prosecutions and seizures it initiated each year for adulterated and misbranded foods, drugs, and stock feeds. From 1919 to 1929, these reports included more disaggregated data on the number of prosecutions and seizures initiated by the agency for particular food and drug products. An examination of cross-product variation in the frequency of seizures and prosecutions may help inform us about what exactly the FDA was targeting in its enforcement work. This analysis is important because it helps establish my claim that the FDA was in fact interested in improving the efficiency of food and drug markets.

For many products, it was difficult for consumers to know the truthfulness of product labels ex ante and even ex post. Without reasonably sophisticated tools, it was hard for consumers to know if glucose had been added to their honey or maple syrup, if their canned vegetables had been watered down slightly, or if small quantities of fat had been skimmed from their dairy. Indeed, without such tools, it was not possible for consumers to know if their milk was free from bacteria, or if their bottled water was contaminated. Hence,  

12. Since I have assumed that \(p_h - c_h > p_I - c_h\), inequality (5) will hold even without any threat of ex post deterrence. Hence, the availability of certification eliminates the FDA’s need to rely on deterrence. The agency, however, may still engage in some deterrence as an auditing mechanism. An important issue here is what commits the regulator not to fine firms that comply ex ante, given that it might be politically profitable ex post for the firm to levy fines with which it is familiar. Several factors constrained this sort of opportunism. First, because the deterrence provisions of the law were weak, it was generally very costly for the agency to fine firms in the first place. Second, compliance (certainly with respect to certification) was generally quite observable: a “stamp of approval,” for instance, could easily be observed by the general public. This would put some limit on the agency’s ability to renege on any implicit contract with firms. Finally, the agency’s concern for its reputation would also constrain its willingness to behave opportunistically. Developing a good reputation among consumers as well as producers was likely in the agency’s interest. Firms may be more willing to comply with an agency that has a reputation for being impartial and professional than one that is known to behave opportunistically.

13. The FDA’s Annual Reports are contained in Dunbar (1951).

14. Unfortunately, the FDA’s Annual Reports do not include quantitative data on its enforcement work between 1907 and 1919.
if the FDA was attempting to use its enforcement authority to improve the accuracy of product labels and to reduce the incidence of unsafe foods, then presumably seizures and prosecutions should have been greater for those products about which the ability of firms to deceive consumers about product quality was greatest. Products like canned fruits and vegetables, canned seafood, and dairy products should therefore show up more frequently than other items in the enforcement data. Table 1 presents information about the total number of seizures and prosecutions by general product category (foods, drugs, and stock feeds) from 1919 to 1938. The data indicate that the FDA initiated between 1,000 and 2,500 seizures and prosecutions against food, drug, and stock feed producers each year. While the distribution across general product categories varied from year to year, approximately 65 to 75 percent of all seizures and prosecutions were for food products, 10 to 30 percent were for drugs, and the remaining were for stock feeds. Food products unquestionably received the brunt of the FDA’s punitive enforcement work, followed by drugs and stock feeds. Hence, the data suggest that the primary goal of the FDA during this time was to regulate the food industry, but that drugs were also an important part of the FDA’s enforcement work. Table 2 provides a more disaggregated picture of the FDA’s enforcement work for the decade from 1919 to 1929. Three broad facts emerge from an
examination of these data. First, among the food product groups, fruit and vegetable products, seafood products, oils, and dairy items were subject to the most prosecutions and seizures. Second, among the two drug product groups, proprietary drugs (i.e., patent medicines and proprietary nostrums) were found to violate the law far more frequently than prescription drugs (i.e., druggist preparations). Indeed, for nearly every year in the decade, more prosecutions and seizures were initiated against patent medicines than against any other product group. Third, the distribution of seizures and prosecutions across product groups did not vary much from year to year.

Interestingly, the data in Table 2 indicate that those food products that were most frequently targeted by the FDA were those for which deception about quality was most common. While the data do not allow me to make finer quantitative distinctions, the discussion in the Annual Report suggests that most of the fruit and vegetable products as well as seafood products that were seized by the FDA during these years were canned items, where the potential to be misleading in product labels was particularly great. For instance, in the Annual Report’s discussion of fruit and vegetable products that were seized under the Pure Food and Drugs Act, frequent mention is made of canned tomato products, to which excessive water or chemical preservatives had been added without indication on the product label. Canned seafood products were seized because they were unclean or were “soaked” in water without indication on

### Table 2. Enforcement of the Pure Food and Drugs Act, 1919–29: Seizures and Prosecutions by Product Group

<table>
<thead>
<tr>
<th>Product Group</th>
<th>1919</th>
<th>1921</th>
<th>1923</th>
<th>1925</th>
<th>1927</th>
<th>1929</th>
</tr>
</thead>
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<tr>
<td>Alimentary pastes</td>
<td>12</td>
<td>22</td>
<td>0</td>
<td>1</td>
<td>25</td>
<td>1</td>
</tr>
<tr>
<td>Beverages and beverage products</td>
<td>36</td>
<td>81</td>
<td>14</td>
<td>31</td>
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<td>3</td>
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<tr>
<td>Baked products</td>
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<td>6</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Fruit and vegetable products</td>
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<td>232</td>
<td>208</td>
<td>254</td>
<td>74</td>
<td>162</td>
</tr>
<tr>
<td>Seafood products</td>
<td>85</td>
<td>118</td>
<td>116</td>
<td>210</td>
<td>108</td>
<td>51</td>
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<td>953</td>
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Source: Dunbar (1951) and calculations by the author.
the product label. Similarly, dairy items that were seized by the FDA were often evaporated or condensed milks in which excessive fat had been skimmed. Seizures of dairy products were also often initiated because unacceptable levels of bacteria were found in milk and cream. Indeed, the *Annual Reports* from 1915 to 1925 frequently mention seizures initiated against milk that was dangerous for human consumption because it contained excessive bacteria, or because it was polluted by contaminated water. The fact that the total number of prosecutions and seizures tended to be greater for those items where cheating on quality by manufacturers was easiest or where product quality was dangerously low suggests that the FDA was trying to use its enforcement authority to improve the informational quality of product labels, as well as to enforce minimal safety and quality standards.

Deceptive labeling was also common in the patent medicine and proprietary industry. Patent medicines and proprietary nostrums were drugs that firms marketed directly to consumers. While some patent medicines available at the time had therapeutic potential, most scholars agree that a good portion of the patent medicine trade was in “snake oil” medications that had limited medicinal value (Young, 1967). Patent medicine manufacturers frequently claimed that their products could cure cancer, baldness, diabetes, tuberculosis, impotence, and other ailments, in spite of the fact that medical scientists knew even at that time that these drugs had no curative power with respect to these conditions. Typical among these medicines were products like B & M’s External Remedy, a liniment composed of turpentine, ammonia, water, and eggs that was marketed as a cure for tuberculosis, pneumonia, cancer, diabetes, whooping cough, diphtheria, asthma, bronchitis, and laryngitis, or Microbe Killer, a tonic consisting of 99 percent water and 1 percent sulfuric acid, which claimed to release a gas within the stomach that would cure headaches, worms, measles, malaria, consumption, smallpox, and leprosy (Lamb, 1936; Young, 1967). It was possible for patent medicine makers to make false therapeutic claims regarding the properties of their drugs because an ethic of “self-medication” pervaded popular thinking at the time, and because it was difficult for individuals to attribute improvement in condition to the taking of a particular drug. Patent medicine manufacturers capitalized on this situation by marketing their products as substitutes for physicians’ services.

Virtually all of the FDA’s seizures and prosecutions of proprietary medicines were for drugs that were falsely labeled with respect to therapeutic value. The *Annual Reports* from 1908 to 1938 are replete with references to proprietary remedies that were seized for making “false and misleading” claims about their medicinal potential. For instance, in the 1914 *Annual Report*, the FDA notes that during the year it “paid very great attention to domestic medicines and mineral water bearing false and fraudulent labels. Many citations have been issued and a large number of cases developed” (Dunbar, 1951:324). Similarly, in the 1927 *Annual Report*, the FDA wrote: “The department’s campaign against misbranded patent or proprietary medicines has continued without interruption. This work calls for the consideration of every label, carton, and circular used in connection with the sale of these products,
and in no field of manufacture and sale is the advertising so prolific as in the patent medicine business. Most of the new products encountered were falsely and fraudulently labeled and required either correspondence or personal interview for correction. In a great many cases seizure action and prosecution have been necessary” (Dunbar, 1951:667).

The frequency with which patent medicines appear in the data on prosecutions and seizures is again a reflection of the fact that the FDA believed that one of its most important roles was to police the accuracy of product labels, in this case regarding the therapeutic value of proprietary drugs. As expressed in the 1932 Annual Report: “Fraudulent claims regarding the curative values of remedies have also been regarded by the administration as a definite public health menace. Fraudulent curative claims have been made at one time or another during the 25-year history of the [federal food and drugs] act for practically every disease” (Dunbar, 1951:777). Indeed, the FDA attempted to stem inter-state trade in fraudulent drugs not only by aggressively enforcing the provisions of the Pure Food and Drugs Act, but also by collaborating with the US Post Office in its efforts to prevent the marketing of falsely labeled proprietary remedies in the mail (Young, 1967). For instance, the 1910 Annual Report notes: “The Division of Drugs [within the FDA] has continued to cooperate with the Post-Office Department in its efforts to obtain fraud orders against medicinal agents represented as cures for various maladies sent or prescribed through the mails in violation of the postal laws. To this end the analysis of the samples of medicines used is supplemented by a study of all the claims and representations made for the treatments” (Dunbar, 1951:154). Hence, the FDA’s efforts to regulate the labeling of patent medicines suggest the function that the organization was attempting to serve: to protect public health and to improve the quality of information about medicines.

5. The Failure of Deterrence in Enforcing Regulation

In the economics literature on the enforcement of regulations and laws, deterrence through the threat of punishment ex post plays the primary role in ensuring compliance with regulatory objectives (Polinsky and Shavell, 2000). In the standard enforcement model, economic actors will comply with regulations if the expected penalties from non-compliance exceed the costs of compliance. The expected penalty is an increasing function of the probability of being caught \( (r) \), the probability of being fined if caught \( (s) \), and the size of the fine \( (f) \). In the model developed earlier, a pure deterrence policy will be effective in inducing firms to comply with the law if the expected penalties from non-compliance \( (rsf) \) are greater than the cost-savings from non-compliance \( (ch − cl) \). Did the FDA under the Pure Food and Drugs Act have the capacity to make deterrence an effective enforcement strategy?

Unfortunately, it may be impossible to know precisely the extent to which the FDA relied on deterrence to induce firms to comply with the law, and for two reasons. First, as suggested by the model, the effectiveness of deterrence depends on the size of the expected penalty relative to the cost savings from
non-compliance. Unfortunately, the absence of data on production costs makes it impossible to directly assess the effectiveness of a pure deterrence strategy. Second, the available data on prosecutions and seizures presumably reflects the equilibrium outcome of the FDA’s enforcement activities, not the extent to which deterrence was used to induce compliance with the law. Still, the fact that the maximum penalties available to the FDA were quite low suggests that deterrence could not have been that significant. Manufacturers and distributors of items found violating the law could be fined up to $500 and imprisoned for a maximum of one year for a first offense. Subsequent offenses were punishable by fines of no less than $1,000 and imprisonment for one year.15

Some evidence of size and types of punishments that the FDA imposed on businesses that violated the terms of the Pure Food and Drugs Act is shown in Table 3. These data are taken from Munch and Munch (1955), who examined the Notices of Judgment issued by the FDA for a sample taken from the first 1,000 food and drug cases.16 While the data on fines and seizures are not taken from a “random” sample of food and drug cases, the figures are suggestive of the fact that the penalties that were meted out to food and drug manufacturers who violated the law were quite minimal. In general, very few prison sentences were imposed on food and drug manufacturers. Indeed, for the first 1,000 cases, no prison sentences were imposed on food or drug manufacturers. Additionally, while the courts frequently ordered fines, the fines were quite small. As shown in the table, the fines imposed on food and drug manufacturers who violated the law were generally less than $200.

In addition to imposing fines on manufacturers whose products were found in violation of the law, the FDA could also seize a manufacturer’s products. Historians of the FDA have suggested that the most powerful deterrent the FDA possessed during this period was its authority to seize products found guilty of adulteration or misbranding (Jackson, 1970; Hutt and Hutt, 1984).

15. The FDA also attempted to raise the cost of violating the law by regularly issuing bulletins that published the convictions obtained under the Pure Food and Drugs Act. The available evidence, however, does not suggest that the threat of bad press played much of a role in disciplining firms to comply with the law.

16. Munch and Munch (1956a, 1956b, 1958) examine subsequent Notices of Judgment, but unfortunately they do not report the fines levied in these cases.
Thus, the true “fine” that the FDA could impose on manufacturers was probably greater than merely the legal fine allowed by the law. Unfortunately, it is not possible to estimate the value of the true fine the FDA could impose, since the Notices of Judgment do not indicate the dollar value of goods seized by the FDA. However, the fact that the seizure provisions of the law were strongly opposed by many food and drug manufacturers, and that during the 1920s food and drug manufacturers lobbied for several legislative amendments to the Pure Food and Drugs Act that would have weakened the seizure provisions of the law, suggests that this was probably the most effective deterrence mechanism available to the FDA (Jackson, 1970).

Still, it is difficult to escape the impression that the ability of the FDA to induce compliance with the law through deterrence was limited. For one thing, the FDA was a relatively small organization. In 1928, the FDA’s food and drug inspection force consisted of only 166 professional, 47 sub-professional, and 53 clerical workers located at eighteen inspection stations across the country (Weber, 1928:65). The duties of these officials ranged from collecting and analyzing food and drug samples, to inspecting food and drug manufacturing plants, to conducting administrative as well as investigational work necessary to enforce the Pure Food and Drugs Act. It is hard to imagine how so small an inspection force could effectively deter firms from violating the law. As noted earlier, the cost of non-compliance is a function of the probability of being caught ($r$), the probability of being convicted if caught ($s$), and the size of the fine ($f$) if convicted. Given the size of the food and drug industry relative to the size of the FDA, the probability that the FDA would catch any given offender ($r$) was very small.

Additionally, because the FDA lacked the legal authority to set food standards, the courts were reluctant to convict manufacturers who produced adulterated goods. As noted earlier, under the Pure Food and Drugs Act, food adulteration was defined vaguely as the (unlabeled) addition of mixtures or impurities that would reduce quality, or the sale of foods that were unfit for consumption. While this definition may have served well for classic adulteration cases where there was much agreement as to what constituted adulteration (for instance, the watering down of canned goods, the addition of glucose to syrups, or the substitution of oleomargarine for butter), this definition quickly became inadequate, as advances in food processing and food manufacturing technology made it increasingly difficult to know what constituted a “mixture” or “impurity” that would reduce quality (Hutt and Hutt, 1984). In response to this problem, the FDA’s Food Standards Committee published a series of Food Inspection Decisions that outlined the standards by which the FDA would determine whether or not a product was adulterated or misbranded. Standards were set after extensive consultation with industry and with state food and dairy regulators. These standards were frequently revised.

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17. According to Hutt and Hutt (1984), there was much less ambiguity about the FDA’s ability to seize goods found to be unfit for consumption and harmful for health, or foods to which “filthy, decomposed, or putrid” substances had been added.
in order to take into account changes in the technology of food processing and manufacturing. Unfortunately for the FDA, however, the courts were often inconsistent in their rulings about whether a deviation from the FDA’s food standards was sufficient for a conviction. For instance, in one case, the court ruled that the government could not rest its case on the standards set forth by the Food Standards Committee, while in another, the courts ruled that these standards could be used by the government as a basis for prosecution (see United States v. St. Louis Coffee & Spice Mills, 189 F. 191 (E.D. Mo. 1909) and United States v. Frank, 189 F. 195 (S.D. Ohio 1911). These ambiguities made it less likely that the FDA could successfully prosecute any given food manufacturer or distributor in court (Hutt and Hutt, 1984). This in turn lowered the probability (s) that the FDA could obtain a successful conviction.

Finally, the available data on recidivism suggests that, for those firms determined to violate the law, the expected penalties from non-compliance were not particularly high. For instance, between 1907 and 1935, thirty-five actions were taken against the California Packing Corporation (producers of Del Monte) for violating the adulteration and misbranding provisions of the law. During the same period, fifty-three actions were taken against Libby, McNeill, and Libby, another national producer of canned products. Manufacturers of quack medicines were among the most common repeat offenders. Between 1915 and 1919, twenty-seven actions were taken against the Pabst Chemical Company, producers of Pabst Okay specific drug (Lamb, 1936: 193). Thus, the FDA’s authority to fine manufacturers and seize adulterated and misbranded products did not deter firms from violating the law.

5.1 Compliance through Pure Deterrence: The Case of Patent Medicines
To illustrate why a strategy of pure deterrence was likely to fail, I analyze the FDA’s efforts to regulate the therapeutic claims that patent medicine manufacturers printed on their product labels. The patent medicine industry furnishes a good control case because this was an industry where the FDA’s ability to offer quality certification or direct assistance in improving quality was extremely limited. Although a handful of effective drugs had emerged by the 1930s, the “therapeutic revolution” was still a decade away technologically (Temin, 1980). The FDA therefore had little to offer patent medicine manufacturers in the way of constructive advice about how to improve product quality or quality certification.18 Hence, in its efforts

18. While the FDA’s professional staff was well known for its expertise in the science of food manufacturing and processing, it was less famous for its work on pharmacology. This can probably be attributed to the slow development of pharmacology rather than to a lack of interest on the part of the FDA. The FDA’s Drug Laboratory employed several scientists and physicians who actively investigated the therapeutic claims made by patent medicines. Although these experts agreed that most patent medicines were worthless, the state of pharmacological knowledge was such that they were unable to offer medicine manufacturers the same kinds of services that the FDA’s food scientists could offer food manufacturers.
to induce compliance from this industry, the agency could rely only on deterrence.

Throughout the thirty years during which the Pure Food and Drugs Act was in effect, the FDA tried repeatedly to induce patent medicine manufacturers to be more circumspect about the therapeutic claims they made about their products. The agency, however, encountered several problems when it came to regulating this industry. First, the patent medicine industry was extremely large and geographically dispersed. According to industry sources from the late 1910s, the Proprietary Association (which included the largest patent medicine firms) had approximately 250 members, while the nation as a whole had roughly 3,000 patent medicine and proprietary nostrum firms (Young, 1992). Hence, the probability of catching an individual offender ($r$) was very small.

Second, the courts made it difficult for the FDA to prosecute firms for making false therapeutic claims. Initially, patent medicine firms that made false therapeutic claims about their products were charged under the misbranding provisions of the law. Under the Pure Food and Drugs Act, it was illegal for firms to include on product labels or on packages information that was “false or misleading in any particular.” The FDA interpreted this clause as giving the agency authority to regulate the therapeutic claims that medicine manufacturers printed on their labels. Prosecution of patent medicine producers for making false therapeutic claims, however, was set back as a result of a Supreme Court decision (United States v. Johnson, 221 U.S. 488, 1911) that declared therapeutic effect “subjective” and hence beyond the purview of the law. This limitation on the FDA’s authority was partially alleviated by the Sherley Amendment of 1912, which made it legal for the government to prosecute firms that make false therapeutic claims intended to defraud the consumer. However, since the FDA now had to prove fraud in order to successfully prosecute, it became harder for the FDA to use the courts to punish patent medicine and proprietary nostrum firms for making false therapeutic claims (Lamb, 1936; Young, 1967; Jackson, 1970). Hence, for patent medicines, the probability that the FDA could obtain a successful conviction ($s$) was particularly small. Thus, in an assessment of its drug enforcement work in 1936, the FDA complained that “Claims for pneumonia, influenza, gallstones, rheumatism, Bright’s disease and venereal diseases continue to be made on the labels of medicines that have no value whatever in the treatment of those conditions. The firms resorting to this sort of business find shelter, at least temporarily, in the requirement that the government must prove fraud, and in the inadequate manpower of the Administration, which must cover the coast lines and State borders with a corps of inspectors numbering less than 100” (Dunbar, 1951:864).

Finally, for patent medicine firms, like all firms under the FDA’s jurisdiction, the fines ($f$) that the courts would impose on manufacturers were extremely small. Thus, it is not surprising that, for patent medicine manufacturers, rates of recidivism were high in spite of the fact that patent medicine firms were prosecuted more frequently by the FDA than firms producing in any other branch of the food and drug industries (Young, 1967;
Jackson, 1970). Medicine manufacturers continued to make false and misleading claims about the therapeutic value of their products well into the 1930s, even though the agency continued to bring patent medicine firms to court. Hence, in the 1936 Annual Report, the FDA complained that “It seems incredible that today, 30 years after the passage of the Food and Drugs Act, and 23 years after the enactment of the Sherley amendment, which specifically, extended the misbranding provisions to cover remedial claims, medicines should be found in interstate commerce bearing claims for the treatment of cancer, tuberculosis, and diabetes. Medical authorities are unanimous in holding that there is no known drug cure for them. Any medicine claimed as a cure is a patent fraud” (Dunbar, 1951:846).

6. Alternatives to Deterrence in Enforcing Regulation

How, then, did the FDA attempt to effect compliance? An examination of the other activities that the FDA was pursuing during this period may provide some insight as to how the agency went about obtaining compliance with the law. However, a useful clue about the FDA’s enforcement philosophy is given in the following passage from the 1926 Annual Report:

The Federal food and drugs act is administered on the theory that more is to be accomplished by acting in an advisory capacity under such conditions as will ensure legal products than by accumulating a record of successful prosecutions with attending fines. In this belief the [FDA] is always willing to advise a manufacturer coming to it with an honest desire to comply with the act as to the conditions which he should observe in marketing a fully legal product. It is believed that more effective compliance with the law may be obtained by showing reputable manufacturers how to bring their products into conformity with its terms than by imposing fines or effecting seizures and confiscations after the violation has been committed. Its policy therefore is to pursue educational methods as a preliminary to legal action where this can be done without jeopardizing the public interest or legitimate competitive conditions. (Dunbar, 1951:636)

The above quote suggests two facts worth noting about the FDA’s enforcement policy. The first is an emphasis on the relative effectiveness of ex ante as opposed to ex post enforcement of the Pure Food and Drugs Act. The second is the educational and advisory role the FDA performed in obtaining ex ante compliance. This tone is not unique to the 1926 Annual Report. Similar sentiment is expressed in other years. For instance, the 1928 Annual Report claims that

[O]nly an insignificant portion of the members of the industries concerned deliberately violate the law. Most of them earnestly desire to comply with all reasonable regulations, not only on ethical grounds but also because it is the part of good business. Recognizing this, the
[FDA] has chosen to regard the [federal food and drug law] as corrective rather than punitive, and has adopted an advisory-before-the-fact attitude by offering constructive suggestions which should enable manufacturers to keep their products in compliance with the law. It has not hesitated, however, to initiate proceedings under the law in those instances where the protection of the consumer or negligence or willfulness on the part of the shipper indicated such action to be proper. (Dunbar, 1951:679)

The model developed earlier suggests that for a given expected penalty from cheating on product quality, firms are more likely to comply if the regulatory agency can benefit compliant firms by offering quality certification or direct assistance in improving quality ex ante. By solving the asymmetric information problem about product quality or by offering firms a lower cost technology for producing the higher quality output, an “advisory-before-the-fact” enforcement policy increases the ease of compliance. While the FDA was not able to offer these kinds of benefits to patent medicine firms, it did have considerable expertise in food science and food manufacturing and had the capacity to offer valuable services to food manufacturing firms. Was compliance with the objectives of the law obtained when the FDA was able to offer such services through an ex ante advisory enforcement strategy?19

6.1 Compliance with Quality Certification

In some cases, the FDA’s ability to reduce informational asymmetries about product quality through quality certification played a key role in facilitating compliance.20 Consider, for instance, the agency’s experience in regulating the coal-tar food color industry. As a result of growth in the use of artificial colors in foods during the early 1900s, consumers as well as food manufacturers became increasingly worried about the safety of the dyes that manufacturers used to color their foods. In response to these concerns, a Color Investigation Laboratory was set up within the FDA in 1915 to study the safety of dyes used in commercially prepared foods. Shortly thereafter, a color certification unit was established within the Color Investigation Laboratory to examine commercial food colors and to determine whether or not they met the FDA’s standards of purity and safety. The FDA issued a certificate for each batch of food coloring that met the FDA’s standards. These examinations were not mandatory, but rather were voluntarily initiated at the request of food color manufacturers.

19. It is worth pointing out that the Pure Food and Drugs Act did not mandate ex ante enforcement of the law. Under this law, the FDA did not have the authority to conduct mandatory factory or warehouse inspections. It had the authority only to seize food and drugs produced for interstate sale that were found to violate the law and to prosecute the manufacturers of such items. Hence, the FDA’s ex ante enforcement measures could be conducted only with industry’s cooperation.

20. As the model indicates, by solving the asymmetric information problem, certification eliminates the gains from cheating and allows firms to earn a price premium on their product. Unfortunately, I could not locate price data to test this implication directly.
The anecdotal evidence indicates that this certification program was extremely popular among food manufacturers and coal-tar food color manufacturers because a certificate from the FDA was a low-cost way of signaling quality. In the 1923 *Annual Report*, it is noted that “[m]anufacturers of food products are recognizing more and more the value of certified colors, and the number of firms manufacturing such colors is steadily increasing, as is also the quantity of color offered for certification” (Dunbar, 1951:554). Similarly, the 1925 *Annual Report* states that “[t]he growth of the certification of food colors has been rapid during the past year. This apparently is due not to any increase in the use of food colors but to the fact that a larger proportion of the colors used in food are certified. Food manufacturers are coming more and more to demand that dyes furnished them be certified” (Dunbar, 1951:603).

Some empirical support for these assertions is shown in Table 4, which displays data on the size of the FDA’s voluntary coal-tar certification program from 1923 to 1938. The first three columns display the number of pounds of straight, repacked, and mixed dyes certified by the FDA’s food color certification laboratory. The fourth column shows the total number of batches certified each year. The last two columns show the number of firms submitting their dyes for certification and the number of new firms who submitted their dyes to be certified. Between 1923 and 1929, the number of batches certified by the FDA and the number of coal-tar food color firms that submitted their products for certification roughly doubled. This rapid growth of the volume of food colors voluntarily submitted by industry for FDA certification suggests the significant role that advisory enforcement—in this case, quality certification—could play in facilitating regulatory compliance.

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The shrimp packing industry on the Gulf Coast furnishes another example of how ex ante product certification could help induce compliance with regulatory objectives. During the late 1920s and early 1930s, the reputation of Gulf Coast shrimp declined as a result of carelessness and unsanitary packing practices of certain Gulf Coast shrimp packers. In response to this problem, the shrimp packers from this region sponsored an amendment to the Pure Food and Drugs Act that allowed any packer of seafood shipped in interstate commerce to apply to the FDA for an inspector to supervise the packing operations of his establishment, specifically to “examine and inspect all premises, equipment, methods, materials, containers, and labels used by such applicants in the production of such food” (Dunbar, 1951:814). Seafood packed under FDA supervision was required to bear on the label the statement “Production supervised by US Food and Drug Administration.” Under the regulations set forth under the so-called Seafood Amendment, shrimp packers were required to bear the costs of the inspection service but, so as not to disadvantage smaller shrimp packers, arrangements were made so that several smaller scale packing establishments located in close vicinity could share the cost of a single inspector.

Shrimp packers apparently desired this voluntary inspection service because it was an effective way of assuring consumers of the quality of a very perishable food product. For instance, the 1934 Annual Report notes that “although the provisions of this law are sufficiently broad to apply to all sea food, the legislation was undoubtedly the result of the experience of the shrimp-packing industry which reached the conclusion that in handling a highly perishable sea food the most effective method of insuring a satisfactory product suitable for human consumption is the application of a thorough-going governmental inspection and supervision at the source of production” (Dunbar, 1951:814). Similarly, the 1935 Annual Report writes that “the regulation promulgated under the [Seafood] amendment insures the integrity of the product . . . Not only is this advantageous to the packer but the consumer is more effectively guaranteed a sanitary, safe, and wholesome product . . .” (Dunbar, 1951:838). This sentiment is echoed again the 1936 Annual Report, which claims that “the assurance of wholesomeness and legality conveyed by the [seafood inspection] service has resulted in increased demands from both distributors and consumers that more than compensate for the costs involved” (Dunbar, 1951:863).

Table 5 presents some data that demonstrate the popularity of the inspection services offered under the Seafood Amendment. In 1934, the year the amendment was enacted, 22 shrimp packing establishments requested inspection services. Over 300,000 cases of canned shrimp, representing less than one-quarter of the total production of canned shrimp on the Gulf Coast, were produced under FDA inspection in 1934. By 1937, 51 establishments requested FDA inspection, and approximately 90 percent of all Gulf Coast shrimp bore the statement “[P]roduction supervised by US Food and Drug Administration” on the label. The fact that, within such a short period, nearly all shrimp packed on the Gulf Coast was produced under FDA supervision that was largely financed by the shrimp packers themselves suggests that a stamp of approval from the FDA was a valuable signal of quality.
This enforcement strategy was also very efficient from the FDA’s perspective because ex ante certification reduced the need for ex post enforcement. In its discussion of the Seafood Amendment in 1935, the FDA wrote: “[C]ompliance with the regulations promulgated under the amendment insures the integrity of the products and thus renders the remedial provisions of the [federal food and drug] act unnecessary” (Dunbar, 1951:838). By directly helping the producers of some products overcome informational asymmetries, the FDA was able to efficiently induce compliance with the law.

Accordingly, the evidence from the food coloring and shrimp industries indicates that when the FDA was able to engage in an ex ante advisory enforcement strategy of product quality certification, compliance was generally obtained. Certification, by solving the asymmetric information problem, made it profitable for firms to comply with regulation. Hence, when certification was viable, the FDA could effectively enforce the law even though its ability to engage in deterrence was limited.

6.2 Compliance with Technical Assistance

In other cases, compliance with the law was obtained because the FDA was able to offer producers a lower cost technology for producing higher quality output. As the model predicts, technical assistance, by reducing the gains

<table>
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<th>Year</th>
<th>Number of Plants Inspected</th>
<th>Number of Cases Inspected</th>
<th>Number of Cases Not Inspected</th>
<th>Total Number of Cases</th>
<th>Cost of Inspection per Can of Shrimp</th>
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<td>131,269</td>
<td>1,312,692</td>
<td>Less than 0.25 cent</td>
</tr>
</tbody>
</table>

Source: Dunbar (1951).

21. This is consistent with the model, which predicts that, with quality certification, compliance is self-enforcing even in the absence of deterrence. See footnote 12.

22. In his analysis of LABEL chicken in France, Ménard (1996) discusses how certification clubs, in combination with government regulation, helped improve quality control in the market for high-end chicken. While there are some similarities between the LABEL chicken case and the two cases discussed here (food coloring and shrimp packing), there are also important differences. First, the formal governance structure that binds LABEL chicken producers in France did not exist among shrimp packers or food coloring manufacturers. Second, and perhaps relatedly, enforcement of quality standards was left largely to the certifying club in France, while it was done principally by the regulatory agency in the United States. Because the relevant expertise existed within the FDA but not within industry during this period, it made sense for the agency to undertake the responsibility for enforcement. Had American producers possessed greater expertise and been more tightly organized along “club” lines, the FDA’s enforcement work would have been facilitated.
from cheating on quality, makes compliance more likely. The FDA’s experience in helping canned food manufacturers improve the accuracy of their product labels furnishes one example of how technical assistance facilitated compliance.

Following the enactment of the Net Weight Amendment of 1913, which required all food and drug packages shipped in interstate commerce to be “plainly and conspicuously marked to show the quantity of contents in terms of weight, measure, and numerical count” (Weber, 1928:28), the FDA was inundated with inquiries from canners and other manufacturers of packaged foods about how best to comply with the law. Historians of the food industry have noted the reluctance on the part of American consumers during the early decades of the twentieth century to purchase canned and packaged foods. In the minds of many housewives, these products were synonymous with deception about quality (Strasser, 1989). Indeed, for the first two decades of the century, the can opener was “deemed an evil symbol” (Young, 1992:120). Among the many factors that contributed to consumer suspicions about canned and packaged products was the fact that packaging made it difficult for consumers to determine product quality. Hence, it was not until the late 1920s that the USDA was able to proclaim the can opener the “Boss of the kitchen” (quoted in Young, 1992:121). The Net Weight Amendment presumably helped enlarge the market for canned and packaged foods by reducing asymmetric information about product quality, but the enforcement of this law also created many practical difficulties for both the FDA and industry. Prior to marketing their products, canners and other producers of manufactured foods needed to know how much slack fill they would be allowed, and what “reasonable tolerances” would be permitted under the law. Hence, officials from the FDA, in cooperation with industry, began to study the extent to which natural shrinkage over time, variation in container types, and unintended errors in weighing, measuring, and counting products might contribute to inaccuracies in product labeling. After these studies were conducted, officials from the FDA held classes for manufacturers about how best to comply with this amendment. The level of cooperation that characterized the relationship between the FDA and the food industry over this amendment suggests that many manufacturers complied with this law because the FDA was able to offer them lower cost methods for improving the reliability of their wares and the accuracy of their product labels.

Indeed, in many instances, when industry encountered practical difficulties in marketing its products, industry sought advice from the FDA on how to improve product quality. The FDA’s Food Research Laboratory, set up initially to develop tools that would assist the FDA in detecting adulteration and misbranding, was frequently called upon by industry to help solve practical problems in quality control. Under the direction of Mary E. Pennington, the Food Research Laboratory developed a reputation for its role in educating food manufacturers and distributors in the best methods of cold storage, transportation, and factory sanitation, and for coordinating and conducting research on food handling, processing, and preserving (Robinson, 1990).
A good example of the types of activities in which the Food Research Laboratory was engaged, and how these activities, in turn, facilitated compliance with the law, is furnished by its work on the storage and transportation of poultry products. The growth of long-distance trade in perishable foodstuffs raised many problems in food storage and handling. While technological changes during the late nineteenth century—specifically, the invention of the refrigerated rail car—made it possible for firms to transport perishable products for longer distances, relatively little research had been conducted about the best methods of handling and storing poultry products using this new technology. As a result, spoiled chickens and broken eggs often made their way to market—waste that was costly to the industry and that also led to several seizures under the Pure Food and Drugs Act (Robinson, 1990). In response to these problems, the Food Research Laboratory, in conjunction with members of the poultry, warehousing, and transportation industries, conducted several experiments aimed at discovering the best method for handling cold-storage poultry, eggs, and fish.

This research generated considerable savings for industry. After adopting the Food Research Laboratory’s recommendations, shippers were able to significantly reduce the incidence of damaged eggs. Studies of the breakage of eggs in transit allowed the Food Research Laboratory to give shippers specific advice about “bracing eggs in cases, bracing cases in cars, and bracing, buffing, and shifting cars in transit” (Dunbar, 1951:333). According to the 1916 Annual Report, the adoption of these recommendations reduced the number of damaged eggs entering the New York City market by 50 percent between 1914 and 1915 (Dunbar, 1951:346). Research on the relative merits of wet packing and dry packing of chickens prior to shipment allowed the Food Research Laboratory to definitely recommend against wet packing. The Food Research Laboratory found that “[c]alculating on the 20,000 car-lot basis, wet packing for each car of poultry would cause the consumer to pay chicken prices for about 1,300 pounds of water and to lose down the drains about 300 pounds of the best food material that chicken flesh contains. Such economic losses are too great to pass unnoticed” (Dunbar, 1951:269).

Given the large savings that could be generated from adopting the Food Research Laboratory’s recommendations, it is not surprising that these investigations into handling and storage received the cooperation of industry and generated considerable interest from various segments of the poultry trade. For instance, according to the 1910 Annual Report, “[t]he industries concerned are bringing their problems for solution, and are offering the most hearty cooperation in furthering the work, believing that by the improved methods evolved, not only will losses be prevented, but it will be possible to put a better product on the market. The cooperators include not only associations of poultry dressers and merchants, but also railways, refrigerator transportation companies, and cold-storage warehousemen” (Dunbar, 1951:141).

The information generated from the FDA’s research into poultry handling and processing was made available to industry through a variety of means. For instance, in 1911, FDA officials visited 128 poultry-handling establishments
in Ohio, Indiana, Kentucky, and Tennessee. During these visits, “the general
conditions of the trade were discussed with the shippers with the object of
improving their methods. As a result of the actual work performed in these
establishments, and of the advice given to shippers to use mechanical refrig-
eration for the handling of eggs and the cooling and packing of poultry, the
number of plants using mechanical refrigeration in Kentucky and Tennessee
has increased during the last fiscal year from 2 to 6 and the tonnage of refrig-
eration has increased from 48 to 160 tons” (Dunbar, 1951:266). In the same
year, a commercial poultry exhibit and demonstration was held at the request
of the management of the Tennessee State Fair, where FDA officials gave daily
talks on the optimal handling of poultry and eggs. The FDA’s poultry exhibit
was visited by “shippers desiring information regarding the handling of poul-
try and eggs, railroad men wanting information regarding refrigerative cars,
temperatures and insulation” (Dunbar, 1951:267). Government meat inspec-
tors, cold-storage men, agricultural extension college professors, poultry rais-
ers, editors of poultry and trade papers, veterinarians, and chemists were also
among those who visited the FDA’s exhibit.

The FDA’s experience in regulating the canning and preserving industry
provides yet another illustration of how the FDA, by helping firms improve
the quality of their products through education and research, was able to induce
greater compliance with the law. As an offshoot of its early enforcement work
on canned vegetables, the FDA began to conduct research on the canning
of peas, corn, and tomatoes to determine how different methods of handling
and processing affected spoilage and product quality. According to the 1909
Annual Report, the vegetable canners at this time were “not so familiar . . . with
the effect of handling and processing on the quality of the goods. It is believed
that a large part of the goods on the market are not of so high a grade as they
might be if the effects of each step were better known” (Dunbar, 1951:93).
Hence, in 1911 the FDA initiated a series of investigations aimed at developing
an understanding of all aspects of vegetable canning, from the “proper quantity
of material to use in the can” to “the degree of temperature and length of time
that should be given in processing in order to get the best result in the finished
product” (Dunbar, 1951:228).

Specific attention was paid to canned tomato products like catsup, which
were frequently seized by FDA inspectors for containing filthy and decomposed
substances. In the early 1900s, canned tomato products frequently included
moldy and rotten tomato parts. Quality control was extremely costly, and
the use of spices enabled manufacturers to conceal mold from consumers.
As part of its enforcement work, scientists from the FDA had invented a mold
count method of estimating the amount of decomposed tomato in catsup and
tomato sauce. The FDA helped manufacturers improve product quality by ed-
 ucating cannery workers on the proper use of this mold count technique (Young,
1992:122). By applying this technique to their own products, manufacturers
improved quality at relatively low cost. Hence, by providing technical assis-
tance to firms that reduced the cost of producing a higher quality product,
the FDA was able to facilitate compliance with the Pure Food and Drugs Act.
Finally, problems in maintaining product quality also led to cooperation between the FDA and blueberry canneries in Maine. According to the *Annual Report*, blueberries canned in Maine during the 1923 and 1924 seasons contained maggots, which led to several seizures under the Pure Food and Drugs Act. As a result of the joint efforts of staff specialists from the FDA, state officials, and blueberry canneries, a technology was developed that allowed the canneries to eliminate maggoty blueberries from their product. This technology was quickly adopted by the canneries and resulted in a dramatic improvement in the quality of canned blueberries from Maine. The 1926 *Annual Report* describes the diffusion of this technology as follows:

During the first season after its invention this device was used by a few canners with marked success. During the next season a still larger number of canners used it and had no difficulty in putting up a product that met the requirements of both Federal and State food laws. During the season of 1926 practically all the principal canners adopted means that insured a legal product. Federal and State food inspectors patrolled the canneries to assist in eliminating maggoty blueberries and to see that the canned product in every way met the requirements of the law. Thus the educational methods followed by the Federal and State food officials have been effective in saving an industry great losses and in enabling consumers to obtain a product free from objectionable material. (Dunbar, 1951:636–37)

Therefore, consistent with the predictions of the model, the examples discussed in this section show that, by providing producers with technical assistance that made it cheaper for firms to produce higher quality goods, the FDA could induce compliance in many segments of the food industry, even though its ability to punish non-compliant firms in the courts was limited.

7. Conclusion

In this article I argue that the FDA was concerned with improving the quality of food and drugs available in the marketplace, but that the FDA’s ability to enforce the Pure Food and Drugs Act through deterrence was limited. Inducing compliance with this law through deterrence was difficult because the FDA was a small agency that lacked the authority to set legally binding food and drug standards. The threat of ex post enforcement of the law through the courts was therefore an ineffective deterrent. Faced with this constraint, effective enforcement of the law required that the FDA offer benefits to firms that voluntarily complied with FDA standards. In those segments of the food industry where the agency possessed the expertise to offer valuable services to firms in the way of quality certification or direct assistance in improving product quality, compliance with the law was generally obtained. Hence, the FDA was often able to enforce the law without relying heavily on deterrence. On the other hand, when the FDA was unable to offer benefits to compliant firms
(patent medicines), the only enforcement mechanism available to the FDA was to punish offenders ex post through the courts. But since the deterrence provisions of the law were weak, this strategy generally failed to induce much compliance.

The analysis presented in this article raises important general questions about the behavior of regulators. An advisory policy of certifying product quality and offering firms direct advice on how to improve their products was clearly not part of the original intent of the Pure Food and Drugs Act. It would therefore appear that the FDA’s ability to successfully enforce the law varied not only because of its expertise in food science and food manufacturing, but also because the law did not prescribe how the agency was to allocate its efforts across different products or enforcement approaches. Do regulators often reinterpret laws or adjust their enforcement strategies to suit their needs? Are agencies that are granted greater discretion in enforcement options more likely to obtain compliance? An examination of the relationship between bureaucratic discretion and regulatory compliance in other agencies may inform these issues.

Finally, this article highlights the important role that advisory enforcement activities can play in inducing compliance with regulatory objectives. As noted earlier, the contemporary FDA, EPA, and OSHA spend considerable resources engaging in various forms of advisory enforcement. While the precise reasons for why advisory enforcement is important may be specific to each agency, the evidence from this case study suggests that advisory enforcement may be essential in obtaining compliance when the agency’s ability to engage in deterrence is limited. Given that many contemporary agencies, like the early FDA, find their budgets and their authority constrained by elected officials, perhaps regulators at these agencies have also discovered that effective enforcement requires them to offer more carrots than sticks to the industries they regulate.

References


Robinson, Lisa M. 1990. “Regulating What We Eat: Mary Engle Pennington and the Food Research Laboratory,” 64 Agricultural History 143–53.


